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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/081,408 | 02/21/2002 | Lars Abrahmsen | 13425-053001 | 1557 |
| 26161 | 7590 | 02/24/2004 | EXAMINER | |
| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | | PAK, YONG D |
| | | ART UNIT | | PAPER NUMBER |
| | | 1652 | | |

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/081,408 | ABRAHMSEN ET AL. |
| | Examiner | Art Unit |
| | Yong D Pak | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13, 15 and 17-24 is/are rejected.
- 7) Claim(s) 14 and 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The amendment filed on December 2, 2003, canceling claims 25-26 and amending claim 13, has been entered.

Claims 1-24 are pending.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments filed on December 2, 2003 have been fully considered but they are not persuasive.

Claims 1-10, 15, 17-19 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Huston et al. and Tudyka et al.

Applicants argue that the combined references do not offer a reasonable level of expectation of success. Applicants argue that Smith et al. merely predicts the transmembrane domain of SSAO and fails to demonstrate that a soluble and active SSAO could be produced. However, a skilled artisan would recognize that the transmembrane domain is anchoring the enzyme in the plasma membrane. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success of producing soluble SSAO by truncating the transmembrane domain.

Applicants also argue that the present invention fuses the 3C protease substrate linker to amino acid no. 29 and not amino acid no. 28, the first residue following the

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transmembrane domain. Applicants list several reasons for this rationale. However, upon inspection of the amino acid sequence of SSAO, one of ordinary skill in the art would have also recognized the advantage of fusing the protease linker at position no. 29 for reasons similar to the ones listed by applicants. As applicants have stated, there are numerous proteases in the cell and growth medium that cleaves at arginine residues. To ensure that the fusion partner and SSAO are not cleaved prematurely, it would have been obvious to add the linker at position 29.

Also, the examiner points out that the claims are drawn to any soluble fragments of SSAO and is not drawn solely on soluble SSAO consisting of residues 29-763 of SEQ ID NO:2.

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Huston et al. and Tudyka et al. as applied to claims 1-10, 15, 17-19 and 24 above, and further in view of Zambidis et al.

Applicants argue that Smith, Huston and Tudyka do not provide the skilled artisan with the requisite suggestion or motivation or a reasonable expectation of success to arrive at the instant invention and the reference of Zambidis does not add what is lacking in these references. The examiner disagrees. Smith, Huston and Tudyka do provide the requisite motivation, suggestion and a reasonable expectation of success, as discussed above.

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Claims 12-13 and 20-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Huston et al. and Tudyka et al. as applied to claims 1-10, 15, 17-19 and 24 above, and further in view of Brenda Enzyme Database.

Applicants argue that Smith, Huston and Tudyka do not provide the skilled artisan with the requisite suggestion or motivation or a reasonable expectation of success to arrive at the instant invention and the reference of Brenda does not add what is lacking in these references. The examiner disagrees. Smith, Huston and Tudyka do provide the requisite motivation, suggestion and a reasonable expectation of success, as discussed above.

Allowable Subject Matter

Claims 14 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

AAny inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner

Rebecca E. Prosty
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PRIMARY EXAMINER
GROUP 1600
MW